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FATIGUE LIFE OF PROTAPER NEXT™ INSTRUMENTS, AN *IN VITRO* ANALYSIS

Mariana Soares Maurício Barcelos Vaz

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Caracterização *in vitro* do comportamento à fadiga de limas

ProTaper Next ™

Dissertação orientada pelos Prof. Doutor António Ginjeira e

Prof. Doutor Rui F. Martins (FCT-UNL/DEMI)

Mariana Soares Maurício Barcelos Vaz

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Aos meus pais, a quem devo tudo.

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RESUMO

INTRODUÇÃO: Os instrumentos de níquel-titânio foram introduzidos para facilitar a preparação canalar. A superelasticidade e a memória de forma impulsionaram a incorporação destes materiais na prática clínica ao reduzirem o tempo de trabalho. Estas propriedades revelam-se requisitos fundamentais na preparação de canais com anatomia difícil porque a estrutura dentária é mais facilmente preservada. Apesar das várias vantagens que apresentam, a fratura continua a ser um dos grandes problemas destes instrumentos devido a vários fatores como o *design* da lima, o processo de fabrico, a dinâmica dos movimentos utilizados na instrumentação, a configuração canalar, a técnica de instrumentação, o número de utilizações, a esterilização, entre outros. A fratura dos instrumentos pode ocorrer por torção ou por fadiga. A torção acontece quando, por exemplo, a ponta do instrumento prende no canal e o motor continua a rodar. A fadiga ocorre inesperadamente sem sinais visíveis de deformação. Os fatores que determinam a fadiga cíclica são o raio de curvatura, o ângulo de curvatura, diâmetro e a massa do instrumento, a conicidade, o número de utilizações do instrumento e a experiência do clínico. Existem diversos sistemas de instrumentação mecanizada, com sistemas rotatórios contínuos e sistemas reciprocantes. O sistema ProTaper Next ™ (*Dentsply Maillefer*) foi lançado no mercado em abril de 2013 e foi criado para que o centro de massa e o centro de rotação do instrumento não coincidissem, numa secção retangular. De acordo com os fabricantes estas limas são a convergência de conicidades progressivas no mesmo instrumento, tecnologia M-wire® e a secção que permite um movimento excêntrico. Para os fabricantes, o sistema é recomendado para uso individual para reduzir o risco de fratura, otimizar a eficiência de corte e evitar o risco de infeção cruzada. O objetivo deste estudo foi caracterizar a resistência à fadiga dos instrumentos ProTaper Next ™ e compará-lo com outros sistemas de movimentos contínuos e reciprocantes.

MATERIAIS E MÉTODOS: Foram analisadas 24 limas endodônticas, não utilizadas, de 25 mm, do sistema ProTaper Next ™ que foram agrupadas em três grupos de acordo com o tipo de lima – X1 (n=4), X2 (n=16) ou X3 (n=4). No seguimento dos estudos que têm vindo a ser desenvolvidos na parceria estabelecida entre o departamento de endodontia da Faculdade de Medicina Dentária da Universidade de Lisboa e o

departamento de Engenharia Mecânica da Faculdade de Ciências e Tecnologia da Universidade Nova de Lisboa foi criado um sistema mecânico em que os instrumentos são submetidos a forças que mimetizam o canal radicular. O raio de curvatura estabelecido no sistema foi de 4,7 mm e o ângulo de curvatura de 45º. Cada instrumento foi inserido no contra-ângulo acoplado ao micromotor WaveOne^{TM} e submetido ao teste de fadiga com uma velocidade de rotação de 300 rpm e um binário de 4 N cm. O tempo que a lima demorou a fraturar foi registado visualmente com um cronómetro digital, sempre pelo mesmo operador. Os dados obtidos em relação ao tempo, local de fratura e número de ciclos à fratura foram estatisticamente analisados pelo teste não-paramétrico de Kruskall-Wallis. Os dados relativos ao instrumento X2 foram relacionados com dados do instrumento WaveOne^{TM} Primary através do teste *t* de Student para amostras independentes. A significância estabelecida foi de 95%.

RESULTADOS: Relativamente ao tempo até à fratura e ao número de ciclos à fratura, o instrumento X1 provou estatisticamente ser significativamente maior que os instrumentos X3 e X2, respetivamente com um valor de $p = 0{,}03$. O local de fratura não mostrou estatisticamente ser significativamente diferente de acordo com o tipo de instrumento, com um valor de $p = 0{,}127$. Quando comparados os resultados dos instrumentos X2 com os resultados em relação ao tempo até à fratura dos instrumentos WaveOne^{TM} Primary (realizados na mesma linha de montagem sob as mesmas condições), a diferença mostrou ser estatisticamente significativa, com um valor de $p < 0{,}001$, com os instrumentos X2 a mostrarem necessitar de menos tempo até a fratura ocorrer.

DISCUSSÃO E CONCLUSÕES: Na avaliação da vida à fadiga dos instrumentos ProTaper Next ^{TM}, o tempo até à fratura foi registado e útil para o cálculo do número de ciclos à fadiga. A fadiga cíclica é medida pelo número de cciclos que um instrumento consegue suportar até à fratura. Este valor é cumulativo e relaciona-se com a intensidade das forças compressivas e de tensão que ocorrem na parte do instrumento que se encontra curvada. O instrumento X1 provou estatisticamente ser significativamente mais resistente à fadiga que os instrumentos X2 e X3 respetivamente. O instrumento X2, apesar de ser o instrumento que de acordo com os fabricantes trabalha todo o comprimento do canal tem a média de número de ciclos à fratura mais baixa (389,2 $\pm$ 46,7). Isto poderá estar relacionado com a intenção de criar uma lima mais flexível que tende a ser mais resistente à torção mas menos resistente à

fadiga cíclica. Relativamente ao tempo que os instrumentos aguentaram até à fratura, para o instrumento X1 a média e desvio padrão foi de 233,8 $\pm$ 36,1 segundos, para o instrumento X2 77,8 $\pm$ 9,3 segundos e para o instrumento X3 89,3 $\pm$ 9,5 segundos. O tempo até à fratura revela-se um parâmetro importante a referir porque assume-se como uma informação clínica mais relevante e mais percetível ao clínico do que o número de ciclos até à fratura que o instrumento suporta. Estatisticamente, a localização da fratura não mostrou ser significativamente diferente entre os instrumentos X1, X2 e X3 indicando que este parâmetro não se encontra dependente do tipo de instrumento mas sim de outros fatores como possivelmente o tipo de curvatura e configuração do sistema mecânico. Os autores do presente estudo não consideram preciso comparar um ciclo de um movimento contínuo (360º) com um ciclo num movimento reciprocante (120º). Assim, a comparação entre os dados da WaveOne™ Primary e da X2 foi feita considerando apenas o tempo que as limas demoravam a fraturar. Estatisticamente observou-se haver uma diferença significativamente maior para os instrumentos WaveOne™ Primary o que permite concluir que estes instrumentos aparentam ter maior resistência à fadiga que os instrumentos ProTaper Next ™ X2. Enquanto os primeiros registaram uma média e desvio padrão de 117,5 $\pm$ 32 segundos, X2 registou uma média e desvio padrão em relação ao tempo de 77,8 $\pm$ 9,3 segundos. Comparado com outros sistemas de instrumentação mecanizada com movimentos como ProFile® e ProTaper Universal®, o sistema ProTaper Next ™ sugere ser menos resistente à fadiga. Estudos futuros devem considerar a possibilidade de reproduzir o movimento de vaivém no canal ao invés de se limitarem a uma posição estática do instrumento no canal. Esta forma, apesar de continuar a não ser uma reprodução fiel do procedimento *in vivo* seria mais perto da realidade. Durante a prática clínica, os médicos dentistas devem estar cientes das propriedades mecânicas dos instrumentos selecionados e ter em conta a baixa resistência à fadiga dos instrumentos ProTaper Next ™ quando comparado com outros sistemas de instrumentação.

KEYWORDS: ProTaper Next; resistência à fadiga; instrumentos níquel-titânio; instrumentação mecanizada; endodontia

ABSTRACT

INTRODUCTION: Nickel-titanium instruments were introduced to facilitate canal preparation. Despite several advantages, instrument separation remains a major concern in Endodontics due to several factors. There are several systems of endodontic files and the purpose of this study was to characterize the cyclic fatigue of ProTaper Next ™ instruments, and compare it to other rotary and reciprocating systems.

MATERIAL AND METHODS: Twenty-four rotary nickel-titanium of the ProTaper Next ™ system were used and analyzed in this study. The instruments were divided into three groups whether they were X1, X2 or X3 instruments. A mechanical device was used to simulate the root canal system with a radius of curvature of 4,7 mm and an angle of curvature of 45º. Each instrument was submitted to the test with a rotational speed of 300 rpm and a torque of 4 N cm. The testing time was registered with a digital chronometer until tip separation occured. Data obtained such as time to fracture, fracture length of the instrument tested and number of cycles to fracture were statistically analyzed by the non-parametric Kruskal-Wallis test. ProTaper Next X2 and WaveOne™ Primary data were analyzed with the *t*-student test for independent samples. Significance was set at the 95% confidence level.

RESULTS: X1 instrument proved to be statistically significant more resistant to cyclic fatigue that instruments X3 and X2, respectively.

DISCUSSION AND CONCLUSIONS: Compared with different rotary and reciprocating systems such as WaveOne™, ProFile® and ProTaper Universal®, the ProTaper Next ™ system suggests being less resistant to cyclic fatigue. During clinical practice, clinicians should be aware of the mechanical properties of the instruments chosen and take into account the lower resistance to cyclic fatigue of ProTaper Next ™ files when compared to other instrumentation systems.

KEYWORDS: ProTaper Next; cyclic fatigue; nickel-titanium instruments; rotary preparation; endodontics

1. INTRODUCTION

Endodontology studies the shape, function and health of the pulp and periradicular tissues as long as its pathology, prevention and treatment.(European Society of Endodontology 2006)

The concepts of cleaning and shaping of the root canal system established by Schilder make up, together with tridimensional obturation, the basis of endodontic therapy. (Chaves Craveiro de Melo et al. 2002)

The main goals of chemomechanical root canal preparation are an adequate disinfection – which includes the removal of inner layer of the dentin; the maintenance of the continuous tapered shape development of the root canal with the largest diameter in the cervical third, in order to facilitate irrigation and a tridimensional obturation; smooth dentin walls; apical constriction and preservation of apex position**.**(Kell et al. 2009; Vaudt et al. 2009; Al-Hadlaq et al. 2010; da Silva et al. 2009; Versiani et al. 2011)

Although many technical advances have been made, the canal preparation is still influenced by the highly variable anatomy, especially in oval, flat or curved root canals. (Versiani et al. 2011) The ability to generate a correct spatial 3D conformation of the root canal is intimately related with the properties of the endodontic instruments and it's usually studied as the capacity to maintain the root curvature as long as avoiding iatrogenic complications (file breaking inside the root canal system, ledging or perforation).(Vaudt et al. 2009)

Throughout history there have been numerous concepts, strategies and techniques for preparing canals. In spite of the design of the file, the number of instruments required and the multitude of techniques advocated, endodontic treatment has been typically approached with optimism for probable success. (Ruddle et al. 2013)

1.1. Stainless steel files

Stainless steel files don't oxidize which stays as an advantage to their predecessor, carbon steel files. However, stiffness – the property of a solid body to resist deformation – remains as the great disadvantage of these instruments. It's only natural that a stainless steel file when bended through the curved root canal walls tends to return at its original shape which will produce forces in the anti-curvature wall causing wear and modification of the original route. This usually leads to non-successful instrumentation, lowering the prognosis of the tooth.(Plotino et al. 2009)

1.2. NiTi

In the early 1960s, a nickel-titanium alloy was developed by W. F. Buehlera, a metallurgist at the Naval Ordnance Laboratory. The alloy was named Nitinol as an acronym for the elements the material was composed, which have been found to have unique properties of shape memory and superelasticity – on unloading the material returns to its original shape before deformation.

The nickel-titanium alloys have a nearly equiatomic ratio of nickel and titanium and can exist in various crystallographic forms as showed in Figure 1

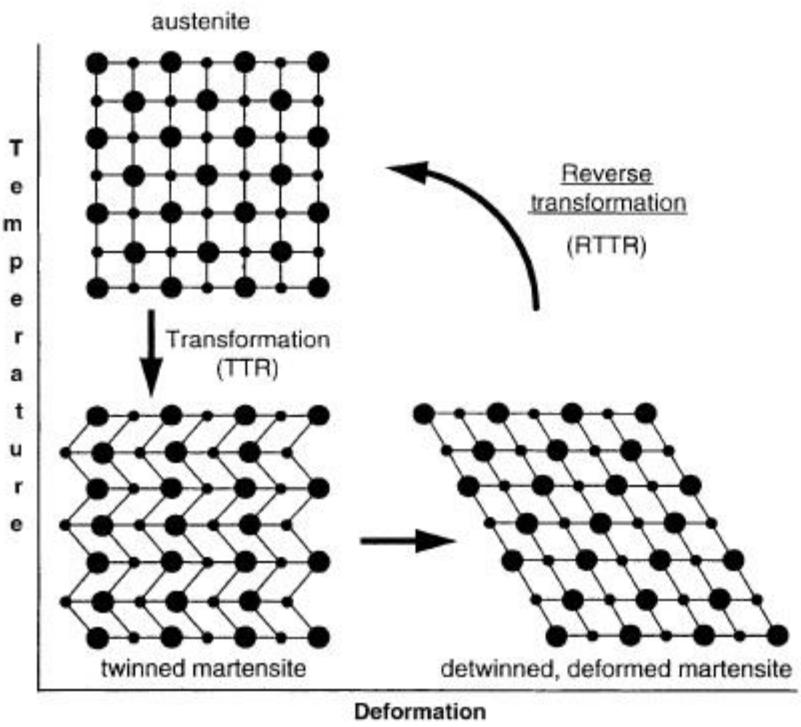

Figure 1 – Diagrammatic representation of the martensitic transformation and shape memory effect of NiTi alloy, from (Thompson 2000)

The generic term for these alloys is 55-nitinol; they have an inherent ability to alter their type of atomic bonding, which causes unique and significant changes in the mechanical properties and crystallographic arrangement. These changes occur as a result of temperature and stress. The two unique features relevant to clinical dentistry occur as a result of the *austenite* to *martensite* transition in the alloy.

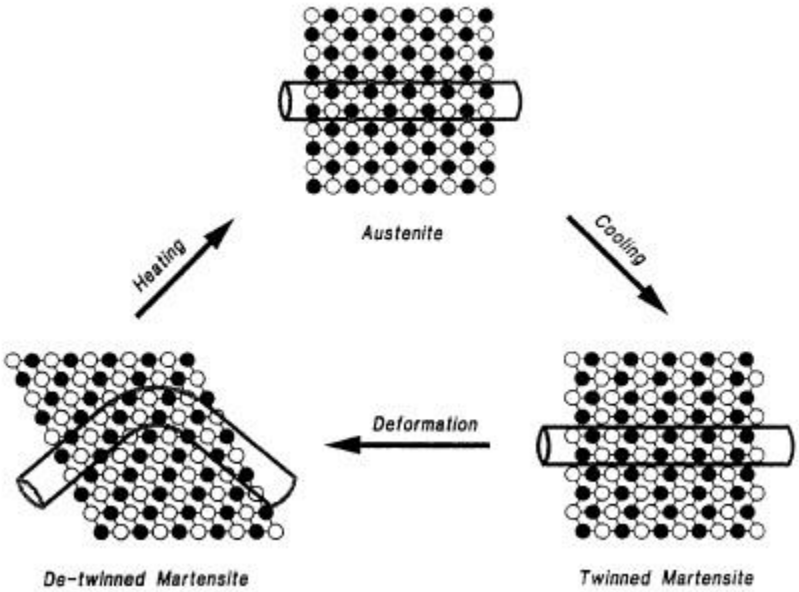

Figure 2 - Diagrammatic representation of the shape memory effect of NiTi alloy, from (Thompson 2000)

In the NiTi alloy system, *austenite* is the parent phase and is typically a stable, body-centered cubic lattice at high temperature ranges (100ºC). Nitinol has the particular characteristic that when it is cooled through a critical transformation range (TTR) shows a dramatic change in its crystallographic arrangement. Consequently, its mechanical resistance (modulus of elasticity and yield strength) and electric resistivity is altered as a result of changes in electron bonding.

The transformation induced in the alloy occurs by a shear type of process that can occur due to alteration of temperature or tension, to a *martensitic* phase. The *martensite* is a flexible, easily deformed, usually named daughter-phase at a low temperature.

When cooled, the alloy gives rise to *twinned martensite* that forms the structure of a closely packed hexagonal lattice. This shape can be deformed easily to a single orientation to *detwinned martensite*. (Figure 2)

The deformation can be reversed by heating the alloy above the TTR. The result is that the properties of the NiTi alloy revert back to their previous higher temperature values, the original parent structure and orientation as body-centered cubic with a stable energy condition. This phenomenon is called *shape memory* and it's possible to use this effect to educate or place the NiTi alloy into a given configuration at a given temperature. In terms of endodontology this phenomenon may translate to the ability to remove any deformation within nickel-titanium instruments by heating them above 125ºC. The *austenite-martensite* can also occur, as mentioned, as the result of tension in the alloy as in the preparation of the root canal. (Thompson 2000)

Superelasticity is associated with the occurrence of a phase transformation of the alloy upon the application of stress above a critical level, which takes place when the ambient temperature is above the so-called *austenite*-finish temperature of the material. (Shen et al. 2011)

A disadvantage of NiTi alloys is its low ultimate tensile and yield strength compared with stainless steel, making it more susceptible to fracture at lower loads. (Parashos & Messer 2006)

1.3. When fracture occurs

Fractured root canal instruments may include endodontic files, lateral or finger spreaders, spiral fillers or Gates-Glidden burs and can be carbon steel, stainless steel, or nickel-titanium. (Spili et al. 2005) Fracture often results due to incorrect use or overuse of an endodontic instrument and seems to occur most commonly in the apical third of the root canal.

While it is a commonly held perception within the dental profession that rotary NiTi instruments have an increased frequency of breakage compared to stainless steel hand files, current clinical evidence does not support this view. (Parashos & Messer 2006) A review of the literature reveals that the mean clinical fracture frequency of rotary NiTi instruments is approximately 1.0 per cent with a range of 0.4–3.7 per cent. In comparison, the mean prevalence of retained fractured endodontic hand instruments (mostly stainless steel files) is approximately 1.6 per cent with a range of 0.7–7.4 per cent.(Young et al. 2007)

Many factors have been linked to the propensity for fracture of rotary NiTi instruments such as instrument design, manufacturing process, dynamics of instrument use, canal configuration, preparation technique, number of uses, cleaning and sterilization procedures. (Parashos & Messer 2006)

Separation of rotary-nickel-titanium instruments takes place by (1) static or dynamic torsional or (2) cyclic fatigue. Trough fractographic analysis of discarded instruments it can be said that:

> (1) torsional failure results in unwinding of the instrument before separation which is characteristic of ductile fracture. It occurs when the tip of the rotating instrument binds in the canal while the motor continues to rotate.
>
> (2) cyclic fatigue occurs unexpectedly and without any visible signs of deformation. The specific factors determining cyclic fatigue include radius of curvature, degree of canal curvature, instrument diameter, taper of instrument, number of times used, instrument mass and operator experience.

Thus, the instrument must have sufficient flexibility to resist cyclic fatigue but also to have sufficient torque strength so separation does not occur if the file binds at its tip. (Johnson et al. 2008)

To improve fracture resistance of NiTi files, manufacturers have introduced new alloys to manufacture NiTi files or developed new manufacturing processes (Shen et al. 2011) and recommend visual inspection before each instrumentation. Another recommendation is to discharge endodontic instruments after a determinate number of uses, but that is no scientific and independent evidence that justifies that recommendation. (Patiño et al. 2005)

1.4. Fatigue tests

Fatigue life is measured by the number of cycles that an instrument bears before fracture, during a fatigue test. It is determined by multiplying rotational speed, in rpm (rotations per minute) by the time the instrument takes to fracture, in minutes. The greater the value of NCF (number of cycles to fracture), the greater is its resistance to fracture. There have been several types of study taking into account this concept, using diverse methodologies and instruments. (Fernandes 2013)

Earlier cyclic fatigue studies have noted the influence of canal shape on instrument breakage. Canal curvature can be expressed by the radius of curvature and the angle of curvature according to the method described by Pruett *et al*. 1997 and as defined in Figure 3. The radius of curvature is the radius of the circle that approaches the curvature of the canal most tightly. The angle of curvature is the angle between two radii of the osculating circle intersecting the end points of the canal curvature. (Wan et al. 2011; Pruett et al. 1997)

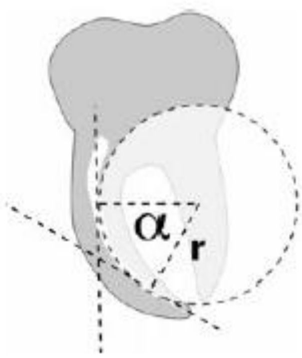

Figure 3 - Radius of curvature (r) and angle of curvature (α), from (Wan et al. 2011)

Recent manufacturing of superelastic files is mostly focused on geometrical details, with emphasis on cross-sectional design. In 2007, *Dentsply Tulsa Dental Specialties*, brought to the market M-Wire® which according to the brand is an alloy thermomechanically processed in order to have a larger flexibility at body temperature and a greater resistance to cyclic fatigue than conventional NiTi wire. (Montalvão et al. 2014; Dentsply Tulsa Dental Specialties 2014)

1.5. The Protaper Next ™ system

The ProTaper Next ™ rotary file system (Figure 4) had its market debut on April 2013 and has been designed such that the center of mass and the center of rotation are off-set as shown on Figure 5. According to the manufacturers, these files are the convergence of three significant design features: progressive percentage tapers on a single file, M-wire® technology and the off-set configuration. The aim of this design was (1) to produce a mechanical wave of motion that travels along the active length of the file, (2) to minimize the engagement between the file and radicular dentin, (3) to enhance collection of debris out of a canal and (4) to improve flexibility along the active portion of the file. There are five files available, in different lengths (21, 25 and 31 mm) for shaping canals, namely X1, X2, X3, X4 and X5, as in Figure 4. These files have, in sequence, yellow, red, blue, double black and double yellow identification rings corresponding to sizes 17/04, 25/06, 30/07, 40/06 and 50/06 respectively. (Ruddle et al. 2013; Dentsply Maillefer 2013)

Figure 4 - This image depicts the 5 ProTaper Next ™ files from (DentsplyMaillefer 2013)

According to the authors ProTaper Next ™ emerged to be ProTaper Universal® system sucessor with many advantages such as:

1. Improved safety with a decreased risk of file breakage;
2. Applicable to difficult clinical cases with enhanced flexibility which makes possible to shape more severely curved narrow canals;
3. Shaping time reduced. Allying shorter clinical sequence, that means less time is spent changing instruments, with high cutting efficiency;
4. M-Wire® technology;
5. Swaggering effect with its innovative off-centred rectangular cross section that gives the file a snake-like "swaggering" movement as it moves trough the root canal (Figure 5).

Manufacturers also advocate that ProTaper Next^{TM} should be for single patient use as the files are packed in pre-sterelised blister packs and have advantages like reduced risk of file breakage, optimal cutting efficiency and no risk for cross contamination. (DentsplyMaillefer 2013)

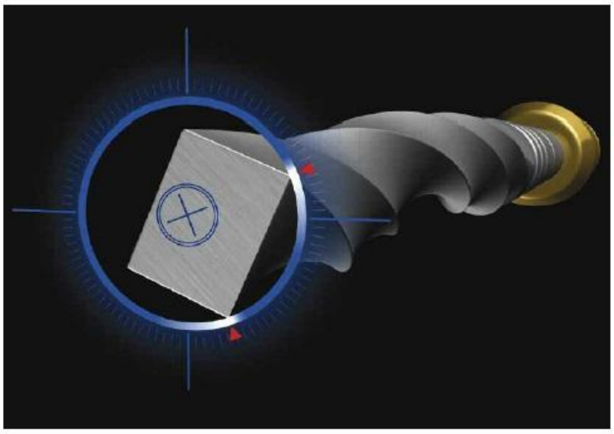

Figure 5 - A cross section of a ProTaper Next^{TM} file whereas an offset mass reduces file engagement, provides space debris and improves flexibility according to the manufacturers, from (Ruddle et al. 2013)

2. AIMS

The aim of this in vitro study is to analyse the fatigue life of niquel-titanium instruments ProTaper Next ™.

Specific goals:

- To compare the fatigue life of instruments X1, X2 and X3.

H0 – the number of cycles until break is alike in all instruments.
H1 – the number of cycles until break is different for X1 instrument.
H2 – the number of cycles until break is different for X2 instrument.
H3 – the number of cycles until break is different for X3 instrument.
H4 – the number of cycles until break is different for all instruments.

- To compare the localization of fracture in instruments X1, X2 and X3.

H0 – the localization of the fracture is alike in all instruments.
H1 – the localization of the fracture is different for X1 instrument.
H2 – the localization of the fracture is different for X2 instrument.
H3 – the localization of the fracture is different for X3 instrument.
H4 – the localization of the fracture is different for all instruments.

- To compare the fatigue life of ProTaper Next™ instruments with WaveOne™ Primary (Dentsply Maillefer ™)

H0 – time until break is alike in both instruments.
H1 – time until break is higher for ProTaper Next™ instruments.
H2 – time until break is higher for WaveOne ™ Primary.

Main goals:

- To compare through bibliographic review the fatigue life of ProTaper Next ™ instruments with ProTaper® and ProFile®.

3. MATERIALS

In this study three types of rotary endodontic instruments, at 25 mm length, were tested from the Protaper Next ™ system (*Dentsply Tulsa Dental Specialties*): X_1 (17/04), X_2 (25/06) and X_3 (30/07), which constituted three experimental groups. All instruments had no pre-utilizations.

The X1 file has a centered mass and axis of rotation from D1-D3 (diameter), whereas from D4-D16 has an offset mass of rotation. Starting at 4%, the X1 file has ten increasing percentage tapers from D1-D11; whereas from D12-D16, there are decreasing percentage tapers to enhance flexibility and conserve radicular dentin during shaping procedures (Ruddle et al. 2013) The same applies to X2 file, starting at a 6% percentage taper. The X3 file has a fixed taper at 7% from D1-D3, then a decreasing percentage tapered design over the rest of their active portions.

Figure 6 - Kit of sterilized X2 files, at 25 mm length, from the Protaper Next ™ system

Figure 7 - Kit of sterilized X1, X2 and X3 files, at 25 mm length, from the Protaper Next ™ system

Files were grouped according to instrument type as shown in chart 1:

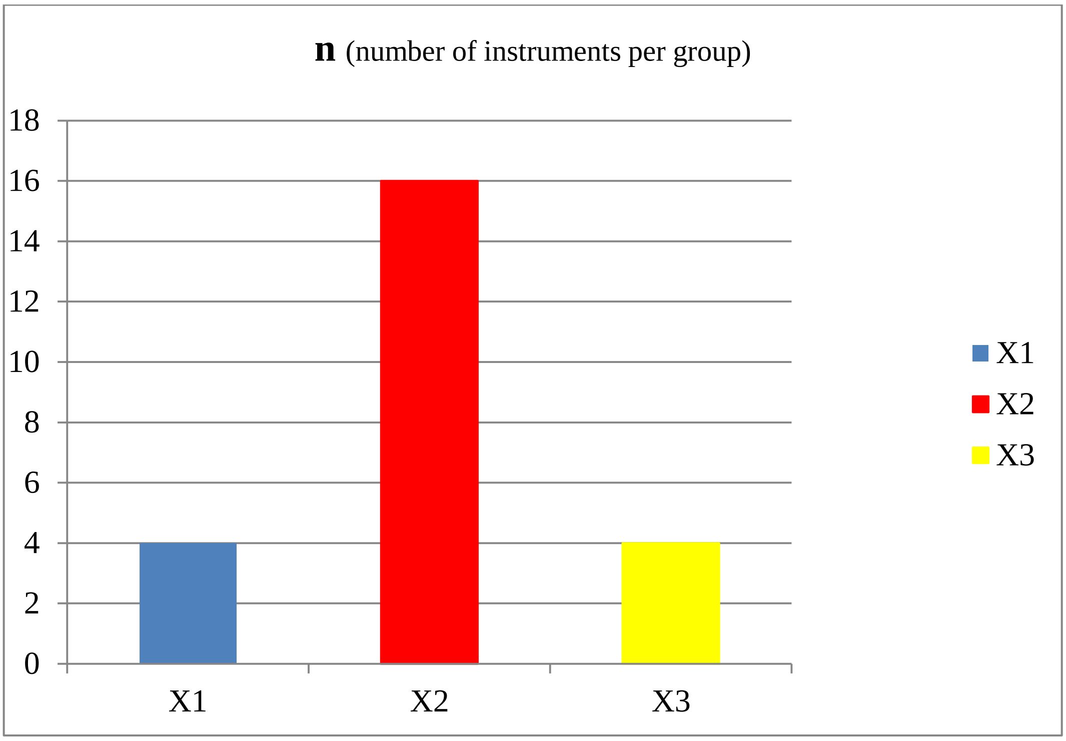

Chart 1 - Number of instruments per group by tipe of file X1, X2 or X3

ProTaper Next ™ instruments were yield by the manufacturer Denstply Maillefer with no further influence in the present study.

The motor used was the WaveOne™ (Denstply Maillefer) in the ProTaper Universal programme at 300 rpm continuous rotary motion and a torque of 4 N cm.

4. METHODS

The instruments were tested to fatigue life in a mechanical system previously created that lead to an assembly line in a partnership between the department of Endodontics in Faculdade de Medicina Dentária da Universidade de Lisboa (Lisbon Dental School) and the Mechanical and Industrial Engineering Department of Faculdade de Ciências e Tecnologia da Universidade Nova de Lisboa. The system recreated bending forces, simulating the inner forces of a root canal. The bending is related with two parameters described previously: the radius and the angle of the curvature. In order to compare data with Pinto 2013, parameters were considered the same has used in that study, meaning:

Angle of curvature - 45º

Radius of curvature - 4,7mm

The geometric drawing is outlined in Figure 8. The instrument enters the mechanical system in (a), it's forced to bend and adjust to the curvature in (b) and its tip is visible in (c). It was necessary to define the W point – coordinates (4,026; 9,026) - that represents the place where the extremity of the instrument should be in each test. It was also necessary to use and tighten three bolts in the prototype to prevent the different pieces to move apart, and to guarantee that the whole system, except the instrument to be tested, was static. All of these parameters guaranteed the repeatability of the tests.

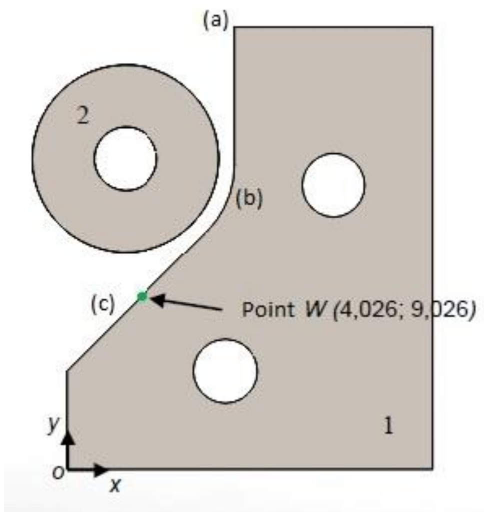

Figure 8 - Schematic representation of the mechanical system adapted from (Pinto 2013)

The piece no. 1 (block) was machined in a CNC machine (computerized numerical control machine) and piece no. 2 (washer) was manufactured from a rod of stainless steel that was machined to a diameter of 4,7 mm and hole-drilled. The stand structure was manufactured from a stainless steel plate with 1,5mm thick with several folding, cutting and welding. The contra-angle of the motor WaveOne ™ (Dentsply Maillefer) was fixed to the metallic stand structure with two plastic pieces adapted to the experimental. (Figure 9)

The all system was supported by a malleable screen of *teflon* and it was fixed to the bench with two staples (figure 10). The testing time was visually registered with a digital chronometer, started at the beginning of the test and stopped at the moment the operator detected instrument separation by observing the displacement of the tip protruding from the artificial canal.

Figure 9 - Image of the experimental assembly where all elements can be seen

Figure 10 - Experimental assembly with the WaveOne™ motor

4.1. Experimental procedure

All instruments were tested with the same procedure following the procedure list as described below:

1- Place the motor in the fixed system;
2- Place the instrument to be tested in the contra-angle and rotate the head of the contra-angle until the instrument is parallel to the bench;
3- Make sure that the instrument is between pieces no. 1 and 2;
4- Adjust the instrument in the X-Y coordinate measuring table (Figure 11) ensuring that it’s perpendicular to the upper part of the block, the instrument is well adjusted between the two pieces and the extremity of the file is well positioned at the W point (Figure 8);
5- Tighten the three bolts and nuts according to the previous adjustments;
6- Turn on the WaveOne ™ motor equipment and select the ProTaper Universal programme;
7- Get the chronometer set up and ready to be use;
8- Step on the pedal initiating the chronometer at the same time, until separation of the instrument occurs;
9- Stop the chronometer when the tip of the instrument comes off;
10- Remove the instrument off the contra-angle and measure the length of the instrument in the coordinate table;
11- Repeat every step with each of the instruments.

Figure 11 – X-Y coordinates measuring table where the mechanical system was set and where all instruments were measured after fracture.

All instruments were tested under the same conditions and by the same operator. In each test the time each file took to fracture was registered *(t)*. As the rotational speed employed in the fatigue test device was 300 rpm, the number of cycles to fracture was calculated using the following formula:

$$NCF = \frac{300t}{60} \Leftrightarrow NCF = 5t$$

The point of fracture in relation to the tip of the instrument was determined by measuring the fractured file with the coordinates table (figure 11).

4.2. Statistical analysis

The statistical analysis was obtained using the IBM ® SPSS ® Statistics version 22.0.0 software. Descriptive statistical analysis was perfomed to each group (X1, X2 and X3). For each experimental group mean, standard deviation and variance were calculated. Data obtained on time, fracture length and NCF were statistically analyzed by the non-parametric Kruskal-Wallis test, after the Kolmogorov-Smirnov and Shapiro-Wilk tests revealed no normality and the Levene test showed no homogeneity. Aditionally ProTaper Next™ X2 and WaveOne™ Primary data were analyzed with the t-student test for independent samples as the Kolmogorov-Smirnov and Shapiro-Wilk tests revealed normality and the Levene test showed the homogeneity of the sample. Significance was set at the 95% confidence level.

5. RESULTS

The results of the experimental procedure regarding time (seconds), fracture length (millimeters) and number of cycles to fracture for each type of file are displayed in table 1.

Type of file	Time (sec)	Fracture length (mm)	NCF
$X1_1$	233,3	3,704	1166,5
$X1_2$	284,2	4,100	1421,0
$X1_3$	217,2	4,030	1086,0
$X1_4$	200,6	3,884	1003,0
$X2_1$	72,1	3,947	360,5
$X2_2$	82,4	4,538	412,0
$X2_3$	82,1	3,853	410,5
$X2_4$	77,5	3,929	387,5
$X2_5$	76,3	4,473	381,5
$X2_6$	98,7	3,965	493,5
$X2_7$	80,6	4,128	403,0
$X2_8$	77,5	4,197	387,5
$X2_9$	80,8	4,123	404,0
$X2_{10}$	84,3	3,721	421,5
$X2_{11}$	79,1	3,774	395,5
$X2_{12}$	76,5	4,040	382,5
$X2_{13}$	78,2	4,036	391,0
$X2_{14}$	81,2	4,035	406,0
$X2_{15}$	62,4	3,901	312,0
$X2_{16}$	55,7	4,163	278,5
$X3_1$	98,6	3,839	493,0
$X3_2$	94,7	4,583	473,5
$X3_3$	77,2	5,172	386,0
$X3_4$	86,8	4,714	434,0

Table 1 - Results for each instrument test for time to fracture (seconds), length of the fractured tip (mm) and Number of Cycles to Fracture.

The mean time, fracture length, NCF and standard deviation for each experimental group are displayed in table 2:

	Type of file	N	Mean ± St. Deviation	Variance
Time	X1	4	233,8 ± 36,1	1306, 1
(sec)	X2	16	77,8 ± 9,3	87,4
	X3	4	89,3 ± 9,5	89, 4
Length of fracture	X1	4	3,9 ± 0,2	0,03
(mm)	X2	16	4,0 ± 0,2	0,05
	X3	4	4,5 ± 0,5	0,3
NCF	X1	4	1169,1 ± 180,7	32651,7
	X2	16	389,2 ± 46,7	2185,2
	X3	4	446,6 ± 47,3	2235,9

Table 2 - Descriptive statistics for time (seconds), length of fracture (mm) and NCF according to each type of file

Time and NCF were found to be statistically significant for all cases (*p*= 0,03). Within each type of file, length of fracture was not found to be statistically different (*p*=0,127). The following histograms represent the data regarding the NCF.

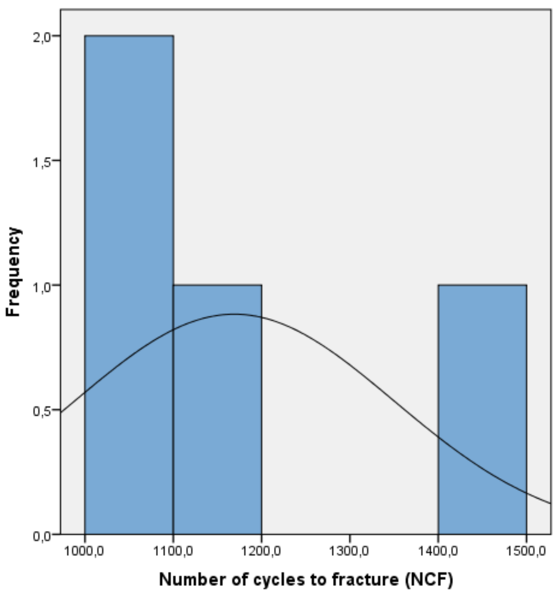

Chart 2 - The distribution of NCF for X1 instrument.

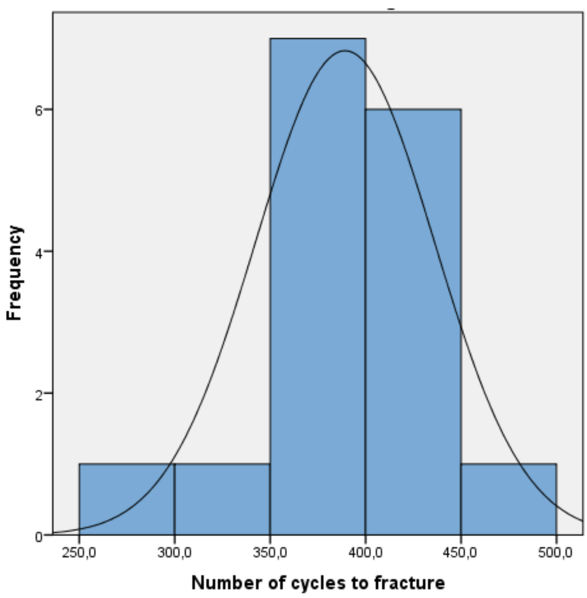

Chart 3 - The distribution of NCF for X2 instrument.

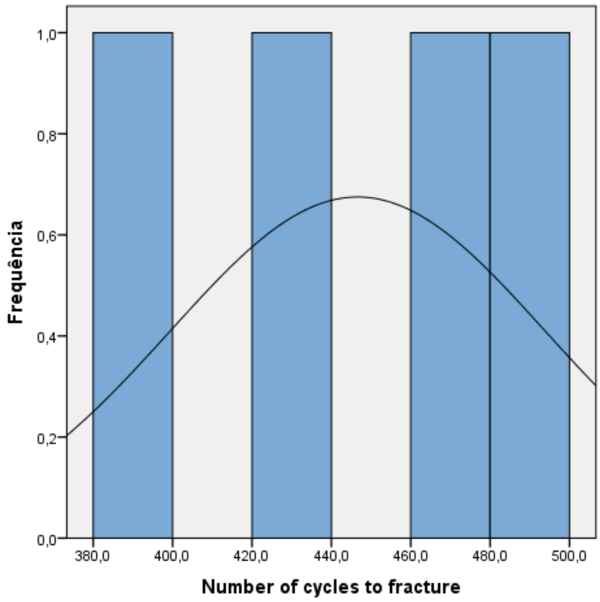

Chart 4 - The distribution of NCF for X3 instrument.

To compare ProTaper Next™ and WaveOne™, data regarding the X2 and the WaveOne™ Primary were selected because X2 and X3 instruments guarantee optimally shaped canals in the majority of times (Ruddle et al. 2013), being X3 optional (Dentsply Maillefer 2013); and WaveOne™ Primary represent the file used in the majority of canals for this system. (Webber et al. 2011) Thus the *t*-student test for independent samples was used when analyzing data and there was a statistically significant difference for each group (p<0,001).

	Type of rotary endodontic fyle	**n**	**Mean ± St. Deviation**
Time (sec)	**ProTaper Next X2**	16	77,8 ± 9,3
	WaveOne Primary	13	117,5 ± 32

Table 3 - Comparision between ProTaper Next™'s instrument X2 and WaveOne™ Primary

6. DISCUSSION

Instrument separation remains a major concern in endodontics as unexpected fracture may occur during clinical practice. (Reddy Y et al. 2014)

This study evaluated cyclic fatigue of a new rotary endodontic instrument ProTaper Next ™.

When evaluating fatigue life of ProTaper Next ™ instruments, time was recorded and useful to calculate NCF. The cyclic fatigue is measured by the number of cycles that an instrument can resist during the fatigue test. The NCF is cumulative and relates to the number of times compressive and tensile stresses occur in the bend portion of the instrument. The X1 instrument proved to be significantly more resistant then X3 and X2, rejecting the null hypothesis (H0). The X2 instrument although representing the file that works the whole length in the canal has the lowest mean of NCF (389,2 $\pm$ 46,7). This may be related with the intent to create a more flexible file with lower mass that tends to withstand torsional fatigue, but to show less resistance to cyclic fatigue.

The mean time and standard deviation for the X1 instrument was 233,8 $\pm$ 36,1 seconds, for instrument X2 77,8 $\pm$ 9,3 seconds and for X3 instruments 89,3 $\pm$ 9,5 seconds as shown in chart 5.

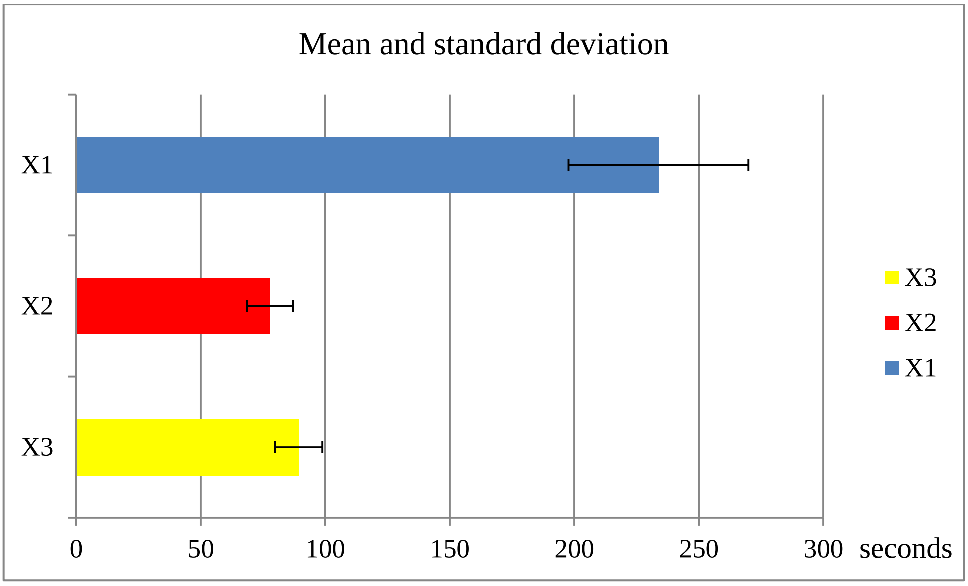

Chart 5 - Mean time and standard deviation for X1, X2 and X3 instruments from the ProTaper Next™ system analyzed

Time to failure is an important parameter to refer as time presents more clinically relevant information as it is much easier for the operator to observe than the number of cycles the instrument endures.

The localization of fracture was not statistically significant for each instrument (*p*=0,127) according to the Kruskal-Wallis for independent samples test which allows to conclude that the type of ProTaper Next™ instruments tested does not influence the point of fracture and this parameter on another factors such as the radius and angle of curvature of the canal and, hence, on the maximum stress induced in the files.

Is important to notice that the sample size for instruments X1 and X3 is small (n=4) and data may not be representative.

As in reciprocating motion the instrument rotates in one direction and reverses direction (Wan et al. 2011) the authors of the present study don't believe it is accurate to compare 360º angular movements (accomplished in a continuous movement) and a 120º angular movement (characteristic of a reciprocating movement) to perform one cycle. Thus the comparison between the rotary and reciprocating system was done in seconds. Comparing the results of WaveOne™ Primary tested by Pinto et al. 2013 with the results of ProTaper Next™ X2 instrument, this study concludes that WaveOne™ Primary has a significant statistically difference comparatively with X2 (*p*<0,001). While WaveOne™ Primary registered a mean and standard deviation of 117,5 $\pm$ 32 seconds, X2 had a mean time to fracture and standard deviation of 77,8 $\pm$ 9,3 seconds.

In order to frame data from this study with the current literature, particularly the work of Ya Shen et al. 2011 with ProFile® files and Ertas et al. 2014 with ProTaper Universal®, Table 3 outlines the type of instrument and conditions used during the experimental procedures in each study as well as the rotational speed employed and results on NCF and time. This table also encompasses the work of Pinto et al. 2013 previously described and analyzed, and the conditions and results of the present ProTaper Next™ study.

As observed in Table 3 both ProFile® and ProTaper Universal® show a higher mean NCF number which suggest that these two rotary systems are more resistant to cyclic fatigue than ProTaper Next™ and allow a safest environment of work to the clinician. WaveOne™ Primary and X2 results have been discussed previously.

Type of file system	Article	Instrument	Testing conditions	Rotational speed	NCF (mean/st. dev)	Time (mean/st. dev)
Profile®	Ya Shen 2011	0.04 taper	4,7 mm radius 45º Dry conditions	300	486 ± 163	---
ProTaper Universal ®	Ertas 2014	F2	5 mm radius 60º Oil for lubrification	250	483 ± 86	---
WaveOne™	Pinto 2013	WO Primary 25mm	4,7 mm radius 45º Dry conditions	320	---	117,5 ± 32
ProTaper Next™	---	X2 25mm	4,7 mm radius 45º Dry conditions	300	389,2 ± 46,7	77,8 ± 9,3

Table 4 – Summarize of the conditions and design of the three studies and their results for each type of file system: ProFile®, ProTaper Universal® and WaveOne™. The design and results for the present ProTaper Next ™ study are also described for a schematic view.

This analysis however is not completely accurate as one must take into consideration the following parameters:

1. Each instrument has a different cross section, mass, and metal surface treatment that can influence cyclic fatigue;
2. The testing conditions for each study are not the same. Same differences regarding angle and radius of curvature of the experimental procedure and lubrication may also be related to higher or lower NCF;
3. Rotational speed employed was not the same for all systems and in all of the studies;
4. Some data depend on operators' accuracy on prosecuting the experimental procedure;
5. Some information is missing in each article in order to compare them with precision.

\ Canals were simulated with a device that guaranteed fixed radii of curvature of the files. This allowed the reproducibly simulation of clinical canal curvature. Values of radius were set at 4,7 mm and angle of curvature at 45º. According to Wan *et al*. 2011 an increase in angle of curvature (more abrupt curvatures) is related with the decrease of time to fracture. While radius of curvature was observed to have a notable effect on instrument life, it was not found to be more significant parameter than angle of curvature. (Wan et al. 2011)

Other important parameter to evaluate when comparing data is the influence of rotational speed on NCF. ProTaper Next ™ instruments in this study were tested under 300 rpm as recommended by the manufacturers. Lopes *et al*. 2009 concluded that the increase in rotational speed significantly reduced the number of cycles to fracture and attributed this factor to the atypical thermomechanical behavior of the NiTi alloy as compared with other metallic alloys. (Lopes et al. 2009) However Pedullá *et al.* 2013 evaluating 120 Mtwo rotary instruments using different rotational speeds concluded that speed did not affect cyclic fatigue of instruments with the same size and taper. (Pedullà et al. 2014) The work of Fernandes 2013, within the same conditions and the same assembly line of the present study, supports that rotational speed plays a major role on fatigue life of the tested instruments, which increases with lowest rotational speed. (Fernandes 2013)

Several factors including operator's handling, method of use, anatomy of the root canal system and the dimension of the NiTi rotary file could influence the propensity of instrument to fracture. (Yum et al. 2011) Despite of the attempt to reproduce the clinical conditions, the test used in this work deviates from clinical practice by certain aspects, which deserve consideration. The in and out movement was not considered as the instrument only rotated in the artificial canal. This meant that maximum deformation always occurred in the same region of the file at the segment where the maximum curvature is located. When the in and out axial movement is considered, the point of maximum fatigue varies continuously which may increase the useful life of the instrument. On the other hand, differences between root canal shape, geometry and curvature from tooth to tooth represent an important variation difficult to copy. The creation of an artificial metal apparatus had the purpose to minimize bias.

In order to enrich this study a posterior analysis of the fractured surfaces of the tested instruments could be done to evaluate the type of fracture and tension points each instrument was submitted to. The possibility to analyze a larger sample of instruments should also be considered to provide more scientific evidence of the conclusions.

Future studies should evaluate the possibility to reproduce the in and out movement of the file into the artificial canal instead of remaining static throughout the test. This would not mimic the root canal preparation but would be closer to the real movement the instrument is submitted to.

Another possibility would be to relate rotational speed with the increase on temperature and consequently on number of cycles to fracture.

7. CONCLUSIONS

Cyclic fatigue has been a major concern in engine driven nickel-titanium instruments.

The purpose of this study was to characterize the cyclic fatigue of ProTaper Next™ instruments, and compare it to other rotary and reciprocating systems.

Regarding the ProTaper Next™ system, X1 instrument showed superior cyclic fatigue resistance when compared with X3 and X2 instruments, respectively. There was also found a significant difference regarding time that each instrument took to fracture (X1>X3>X2). The point where instrument separation occurred was not related to the type of instrument tested.

When comparing data from this study with an analogue, with the same testing conditions and assembly line from WaveOne™ Primary, X2 instrument proved to take less time to break.

This study gives an idea to the clinician about the adequate time and number of cycles to fracture so that instruments can be used more cautiously in severely curved canals.

Compared with different rotary and reciprocating systems such as ProFile® and ProTaper Universal®, the ProTaper Next ™ system suggests being less resistant to cyclic fatigue.

During clinical practice, clinicians should be aware of the mechanical properties of the instruments chosen and take into account the lower resistance to cyclic fatigue of ProTaper Next ™ files when compared to other instrumentation systems.

REFERENCES

Al-Hadlaq, S.M.S., Aljarbou, F.A. & AlThumairy, R.I., 2010. Evaluation of cyclic flexural fatigue of M-wire nickel-titanium rotary instruments. *Journal of endodontics*, 36(2), pp.305–7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/20113796 [Accessed January 27, 2014].

Chaves Craveiro de Melo, M., Guiomar de Azevedo Bahia, M. & Lopes Buono, V.T., 2002. Fatigue resistance of engine-driven rotary nickel-titanium endodontic instruments. *Journal of endodontics*, 28(11), pp.765–9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/12470021.

Dentsply Maillefer, 2013. Protaper Next - flexible performance.

Dentsply Tulsa Dental Specialties, 2014. M-Wire NiTi.

DentsplyMaillefer, 2013. Protaper Next | DentsplyMaillefer. Available at: http://www.protapernext.com/ [Accessed June 9, 2014].

European Society of Endodontology, 2006. Quality guidelines for endodontic treatment: consensus report of the European Society of Endodontology. *International Endodontic Journal*, 39(12), pp.921–930. Available at: http://doi.wiley.com/10.1111/j.1365-2591.2006.01180.x [Accessed February 28, 2014].

Fernandes, A., 2013. *Caracterização do comportamento à fadiga de instrumentos de Ni-Ti para aplicações de endodontia*. Universidade Nova de Lisboa - Faculdade de Ciências e Tecnologia.

Johnson, E. et al., 2008. Comparison between a novel nickel-titanium alloy and 508 nitinol on the cyclic fatigue life of ProFile 25/.04 rotary instruments. *Journal of endodontics*, 34(11), pp.1406–9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/18928858 [Accessed January 27, 2014].

Kell, T. et al., 2009. Torsional profiles of new and used 20/.06 GT series X and GT rotary endodontic instruments. *Journal of endodontics*, 35(9), pp.1278–81. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19720231 [Accessed January 27, 2014].

Lopes, H.P. et al., 2009. Influence of rotational speed on the cyclic fatigue of rotary nickel-titanium endodontic instruments. *Journal of endodontics*, 35(7), pp.1013–6. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19567325 [Accessed February 28, 2014].

Montalvão, D. et al., 2014. Structural Characterisation and Mechanical FE Analysis of Conventional and M-Wire Ni-Ti Alloys Used in Endodontic Rotary Instruments. *TheScientificWorldJournal*, 2014, p.976459. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3918393&tool=pmcentrez&rendertype=abstract.

Parashos, P. & Messer, H.H., 2006. Rotary NiTi instrument fracture and its consequences. *Journal of endodontics*, 32(11), pp.1031–43. Available at: http://www.ncbi.nlm.nih.gov/pubmed/17055902 [Accessed February 21, 2014].

Patiño, P.V. et al., 2005. The influence of a manual glide path on the separation rate of NiTi rotary instruments. *Journal of endodontics*, 31(2), pp.114–6. Available at: http://www.ncbi.nlm.nih.gov/pubmed/15671822 [Accessed February 21, 2014].

Pedullà, E. et al., 2014. Influence of rotational speed on the cyclic fatigue of Mtwo instruments. *International endodontic journal*, 47(6), pp.514–9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/23992374 [Accessed June 7, 2014].

Pinto, P., 2013. *Avaliação da vida à fadiga de instrumentos endodônticos submetidos a movimento reciprocante*. Universidade Nova de Lisboa - Faculdade de Ciências e Tecnologia.

Plotino, G. et al., 2009. A review of cyclic fatigue testing of nickel-titanium rotary instruments. *Journal of endodontics*, 35(11), pp.1469–76. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19840633 [Accessed January 27, 2014].

Pruett, J.P., Clement, D.J. & Carnes, D.L., 1997. Cyclic fatigue testing of nickel-titanium endodontic instruments. *Journal of endodontics*, 23(2), pp.77–85. Available at: http://www.ncbi.nlm.nih.gov/pubmed/9220735.

Reddy Y, P., S, K. & Subbarao, C. V, 2014. Cyclic fatigue testing of three different rotary nickel titanium endodontic instruments in simulated curved canals - an in vitro sem analysis. *Journal of clinical and diagnostic research : JCDR*, 8(2), pp.211–3. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3972566&tool=pmcentrez&rendertype=abstract [Accessed June 7, 2014].

Ruddle, C.J., Machtou, P. & West, J.D., 2013. The shaping movement 5th generation technology. , (April), pp.1–8.

Shen, Y. et al., 2011. Fatigue testing of controlled memory wire nickel-titanium rotary instruments. *Journal of endodontics*, 37(7), pp.997–1001. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21689559 [Accessed February 21, 2014].

Da Silva, K.T. et al., 2009. Wear promoted in the apical third of simulated canals after instrumentation with ProTaper universal system. *Journal of applied oral science : revista FOB*, 17(5), pp.501–7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19936533.

Spili, P., Parashos, P. & Messer, H.H., 2005. The impact of instrument fracture on outcome of endodontic treatment. *Journal of endodontics*, 31(12), pp.845–50. Available at: http://www.ncbi.nlm.nih.gov/pubmed/16306815.

Thompson, S.A., 2000. An overview of nickel – titanium alloys used in dentistry. , 44(0), pp.297–310.

Vaudt, J. et al., 2009. Ex vivo study on root canal instrumentation of two rotary nickel-titanium systems in comparison to stainless steel hand instruments. *International endodontic journal*, 42(1), pp.22–33. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19125977 [Accessed February 21, 2014].

Versiani, M.A., Pécora, J.D. & de Sousa-Neto, M.D., 2011. Flat-oval root canal preparation with self-adjusting file instrument: a micro-computed tomography study. *Journal of endodontics*, 37(7), pp.1002–7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21689560 [Accessed February 21, 2014].

Wan, J. et al., 2011. A comparison of cyclic fatigue resistance in reciprocating and rotary nickel-titanium instruments. *Australian endodontic journal : the journal of the Australian Society of Endodontology Inc*, 37(3), pp.122–7. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22117719 [Accessed February 26, 2014].

Webber, A.J. et al., 2011. The WaveOne single-file reciprocating system. , pp.28–33.

Young, G.R., Parashos, P. & Messer, H.H., 2007. The principles of techniques for cleaning root canals. *Australian dental journal*, 52(1 Suppl), pp.S52–63. Available at: http://www.ncbi.nlm.nih.gov/pubmed/17546862.

Yum, J. et al., 2011. Torsional strength and toughness of nickel-titanium rotary files. *Journal of endodontics*, 37(3), pp.382–6. Available at: http://www.ncbi.nlm.nih.gov/pubmed/21329826 [Accessed January 27, 2014].

APPENDIX

Abbreviations

3D - tridimensional
CNC - computerized numerical control
D - diameter
NCF - number of cycles to fracture
NiTi - nickel-titanium
RTTR - reverse transformation temperature range
TTR - transformation temperature range

Symbols

% - percentage
n - number of sample
p - significance
® - registered trademark
™ - unregistered trademark

Units

º - degrees
ºC - degree Celsius
mm - millimeters
N cm - Newton centimeter
rpm - rotations per minute

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